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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,200	01/02/2002	John C Rogers	P 283207	9600
909	7590	02/23/2005	EXAMINER	
PILLSBURY WINTHROP, LLP			MORAN, MARJORIE A	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	
			1631	
DATE MAILED: 02/23/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,200	Applicant(s) ROGERS, JOHN C	
	Examiner Marjorie A. Moran	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claims 1-9 are pending. All objections and rejections not reiterated below are hereby withdrawn.

Priority

If applicant desires benefit of a previously filed application under 35 U.S.C. 119, 120, or 365, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence(s) of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. ____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the

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application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

It is noted that although priority to a provisional application is claimed, the instant specification does not disclose any priority information.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4 and 7 recite the term “affected sequence data” each in the second paragraph of the claim. Claims 3, 6, and 9 similarly recite the terms “affected sequence data” and “affected biological catalyst”. The term “affected” is not defined by the specification, and it is unclear what the sequence data or catalysts are intended to be “affected” by, therefore the claims are indefinite. It is noted that page 7 of the specification discloses that gene *clusters* may be “substantially affected” wherein the term “affected” appears to mean repressed or induced; however, it is unclear whether this is the definition application intends for the *sequence data or biological catalyst* of the claims. As catalysts are usually inhibited or activated, but NOT repressed or induced, it is further unclear what the term “affected” is intended to mean with regard to a catalyst. In the event that applicant does intend “affected” to mean repressed or induced with regard to sequence data, then the claim is still indefinite, as set forth above, as it is still unclear what the sequence data (or catalyst) is suppressed or induced BY.

Claims 1 and 4 each recite an intended use (for the system) or intended result (for the method) in the preamble; “to model a physiological response of biological cells.” However, the system of claim 1 is not limited to comprise any model or “capability” for designing, generating, etc. a model of a physiological response of biological cells, nor is

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the system limited to comprise information with regard to biological cells. Similarly, the method of claim 4 fails to recite any steps of modeling, using a model, to predict or determine a physiological response of biological cells. It is noted that metabolic pathways may be derived from experimental data performed on biological cells, or may be used to predict the change in function of biological cells; e.g. using flux balance analysis based on metabolic data, therefore the claims are enabled for the intended uses; however, as no actual limitations with regard to modeling or biological cells are recited in the claims, it is unclear what limitation of the system or method applicant intends by the intended use/result recited, therefore the claims are indefinite.

Claims 1 and 4 are directed to a system and method "for managing and presenting information derived from differential expression of genetic information" as set forth in the preamble of each claim. However, neither claim actually recites any limitation with regard to differentially expressed genes or data derived from differential expression, etc. The claims do limit "sequence data" to represent "a direction and magnitude of regulation"; however, "regulation" of sequences is not necessarily the same as "differential expression," and the terms are regarded as having different meanings in the art. It is further noted that not all "sequence data" is genetic. It is well known in the art, for example, that protein expression may be regulated at both or either of transcription and/or translation, or post-translation (e.g. quaternary structure formation may be regulated). As it is unclear whether applicant actually intends a system/method for managing and presenting data derived from a "differential expression of genetic information," the claims are indefinite.

Claims 1, 4, and 7 limit metabolic pathways to comprise at certain ones of said locations “respective” graphical representations of a reaction and associated information for the reaction. It is unclear what the reactions are intended to be “respective” to; i.e. a specific (certain one) location, a metabolic pathway, the reaction itself, etc. As the limitation intended by the entirety of the phrase following “pathways” is unclear, the claims are indefinite.

Claims 1, 4, and 7 recite a step or mechanism for performing a step of linking “previously generated” sets of “affected” sequence data to catalyst information. As no “previous” step of generating “affected” sequence data is recited in the claims, it is unclear what data is intended to be linked to the catalyst information, and the claims are indefinite.

Claims 2, 5, and 8 recite a mechanism or step of assigning “a corresponding grade” to a “corresponding region”. The double use of “corresponding” renders it unclear whether the grade and region are intended to correspond only to each other, or if the grade or region, or both, are also intended to correspond to something else. As the limitation intended by applicant is unclear, the claims are indefinite.

Claims 2, 5, and 8 recite assigning a grade to a region “in accordance with” a number of sets of data linked to the region. The examiner interprets “assigning a grade” to mean ranking. However, it is unclear what limitation is intended by “in accordance with” and no actual limitations for classifying or ranking are recited. It is unclear what parameters are to be used for assigning the recited grade. In the event that applicant intends that the “grade” be based on how many sets of sequence data are linked to a

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region, then the claim is still indefinite as it is unclear what the "grade" represents. I.e. Do more linked sets produce a higher rank or "better" grade? Or if a region is linked to more sequence sets, is it accorded a lower rank or "poorer" grade? It is further unclear what meaning is to be attributed to the grading or ranking. For these reasons, the claims are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-9 are rejected under 35 U.S.C. 102(a) as being anticipated by OGATA et al. (Nucleic Acids Research (1/1/1999) vol. 27, no.1, pages 29-34).

OGATA teaches a computerized system and method for managing and presenting metabolic data comprising providing/displaying a map of metabolic pathways comprising regions and locations (p. 31, Fig. 1), and wherein each region is defined by coordinates (see p. 31 and Table 1). OGATA's database comprises a tool for computing enzymatic reactions, including substrates and products (p. 34, left column) and associates genes with enzymes (p. 30, right column). OGATA further teaches that genome information and gene order is linked to his pathway map (p. 32, right column) and teaches that his database includes gene regulatory information (p. 33, right column: Functional Genomics), thus anticipating claims 1, 3-4 and 6. As use of OGATA's

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system inherently requires entering instructions onto a computer-readable medium, claims 7 and 9 are also anticipated. OGATA teaches that his database/system may hierarchically classify (i.e. "grade") genes (p. 32, left column). As the gene information is linked to the KEGG database, then OGATA's grading of genes is inherently a grading or hierarchical designation for the associated metabolic pathway or region, and claims 2, 5, and 8 are anticipated.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur: 7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
2/22/05